

REMARKS/ARGUMENTS

This response and Request for Continued Examination is in response to the Final Office Action dated January 10, 2006. An Extension of Time is also hereby submitted extended the deadline for response to June 10, 2006. Claims 1-16 are pending in this application.

Rejection Under 35 USC §103(a)

Claims 1-16 are rejected under 35 USC §103(a) as being unpatentable over Okada *et al.* (U.S. Patent No. 4,323,326) in view of Schwartzman *et al.* (U.S. Patent No. 4,125,050). Applicants respectfully submit that the Examiner has not established *prima facie* obviousness of claims 1-16 in view of the cited references, as these references, either alone or in combination, do not teach or suggest each and every element of the invention as presently claimed.

In support of Applicant's arguments, Applicants enclose herein Exhibits 1-3 containing photographs of the claimed invention, and a declaration from the inventor to assist in the examination of the pending claims.

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application." See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. See *id.* Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. See *WMS Gaming Inc. v. International Game Technology*, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The

suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. See *id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like to motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. See *id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims, See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000). If any one of these three factors is not met, the PTO has failed to establish a *prima facie* case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

If the cited prior art fails in one of these three areas, a *prima facie* case of obviousness has not been established.

Independent claims 1, 7 and 11 of the instant application recite a self-drilling bone screw having a generally flat cutting edge. None of the cited references, either alone in combination, teach or suggest all the aspects of the self-drilling bone screw recited in claim 1. The generally flat cutting edge is disclosed in the specification, as filed, on page 3, line 28 to page 4 line 2. Applicants have provided photographs of the claimed bone screw showing this generally flat cutting edge in Exhibits 1-3. Exhibit 1 depicts the bone screw generally as depicted in Figure 1 in the application as filed. Exhibit 2 depicts the flat cutting tip 16 as depicted in Figure 1. Exhibit 3 depicts a higher magnification of the flat cutting tip 16 depicted in Exhibit 2 and Figure 1. A declaration from inventor Robin C. Whitmore verifying that the photographs depict the self-drilling bone screw as disclosed in the specification as originally filed and as presently claimed and particularly pointing out the differences between the claimed self-drilling screw and the cited prior art is attached herein.

Specifically, claims 1, 7 and 11 all recite a self-drilling bone screw, comprising a body having a head at one end and a tip defining a single generally flat cutting edge at an opposite end thereof disposed generally perpendicular to a central longitudinal axis of the body. Neither Okada *et al.* nor Schwartzman *et al.* teach or suggest all these aspects of the self-drilling bone screw.

Okada *et al.* teach a self-drilling screw comprising a body having a head at one end and a tip at the other end, and dual lead threads. Okada *et al.* do not disclose a single flat cutting edge extending generally perpendicular to a central longitudinal axis of the body.

The deficiencies of Okada *et al.* are not remedied by Schwartzman *et al.* The Examiner states that "Schwartzman *et al.* disclose a self-drilling screw 10 having an angled cutting tip similar to Okada *et al.*, and in addition, a single, flat, transverse cutting tip 40 at an extreme end in order to substantially reduce the friction and drag on the entire drilling point and to help the screw to stabilize quickly and have little or no tendency to walk during the starting of the drilling operation." Applicants respectfully disagree with the Examiner's interpretation of the disclosure of Schwartzman *et al.* Schwartzman *et al.* describes the screw tip as being formed with "longitudinally extending flutes located substantially on opposite sites of the body, these flutes defining rectilinear tip and side cutting edges positioned along opposite sides of the body, the tip cutting edges being forwardly offset and angularly diverging from the ends of a transverse cutting edge, formed on a tip web..." (Abstract).

Schwartzman *et al.* do not disclose a tip defining a single generally flat cutting edge disposed generally perpendicular to a central longitudinal axis of the body, as do claims 1, 7 and 11 of the instant application and as further demonstrated in Exhibit 3 attached hereto which clearly disclose and depict a flat cutting edge. The Examiner particularly points out Figures 1 and 2 of Schwartzman *et al.* The tip web disclosed in general in Figures 1 and 2 of Schwartzman *et al.* is specifically illustrated in Figure 3. The screw tip illustrated in Figure 3, which is the only figure to specifically show the screw tip, has a transverse cutting edge, but does not have a flat cutting edge

perpendicular to the central longitudinal axis of the body of the screw. In fact, the word flat is found four times in Schwartzman *et al.* (column 3 lines 35, 43, 45 and 46), each time in reference to the relief surfaces, not the cutting tip. Additionally, the textual description of the screw tip, generally in column 2, lines 4-11 and more specifically at column 3 lines 1-17, defines a screw tip having a "transverse extending point-cutting edge 38" but no flat cutting edge perpendicular to the central longitudinal axis of the body of the screw. Therefore Schwartzman *et al.* do not disclose a single flat cutting edge extending generally perpendicular to a central longitudinal axis of the body.

As depicted in the attached Exhibits and stated in the Declaration from inventor Robin C. Whitmore, neither of the two cited prior art references disclose the self-drilling, self-tapping bone screw having a flat cutting tip as claimed in the instant application. Specifically, Figures 1A, 1B, 3 and 5 of Okada *et al.* depict a self-drilling screw with a pointed cutting tip generated at the intersection of end faces 8 and 9. Figure 1 of the instant application and Exhibits 2 and 3 demonstrate that the claimed self-drilling bone screw has a flat cutting edge. Additionally, as can be seen in Figure 3 of Schwartzman *et al.*, the prior art screw does not have a flat cutting edge. The depiction of the self-drilling screw of Schwartzman *et al.*, in Figure 3 is confirmed by the description of the cutting tip in column 3 lines 1-6, "As best shown in FIG. 3, the tip-cutting edges, 34, 34, are forwardly offset and lie in substantially parallel planes. At their inner ends, the tip-cutting edges extend outwardly in diverging directions from the ends of a transversely extending point-cutting edge 38 formed on an interconnecting tip web 40." Figure 1 of the instant application and Exhibits 2 and 3 clearly define a flat cutting edge which is perpendicular to the central longitudinal axis of the body of the screw.

In view of the foregoing, Applicants respectfully submit that neither of Okada *et al.* and Schwartzman *et al.*, either alone or in combination, teach or suggest a self-drilling bone screw having a tip defining a single flat cutting edge extending generally perpendicular to a central longitudinal axis of the body. Therefore Applicants respectfully submit that the cited references do not teach each and every element of independent claims 1, 7 and 11 and therefore the Examiner cannot establish *prima facie* obviousness of these claims. Because each of the remaining claims depends from one

of claims 1, 7 or 11, Applicants respectfully submit that the Examiner cannot establish *prima facie* obviousness of claims 2-6, 8-10 and 12-16 as well. Accordingly, Applicants respectfully submit that claims 1-16 are not obvious under 35 USC §103(a) and earnestly request the withdrawal of the outstanding rejection on this basis.


Conclusion

Applicants believe that pending claims 1-16 satisfy all the requirements for patentability and are in condition for allowance. A timely indication of same and passage of the claims to issuance is therefore respectfully requested.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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